## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

\*

ANDERSON et al. \* Group Art Unit: Unassigned

\*

Application Serial No. (Unassigned) \* Examiner: Unassigned

\*

Filed: July 25, 2001

Title: THERAPEUTIC APPLICATION OF CHIMERIC AND RADIOLABELLED ANTIBODIES TO HUMAN B LYMPHOCYTE RESTRICTED DIFFERENTIATION ANTIGEN FOR TREATMENT OF B CELL LYMPHOMA

## PRELIMINARY AMENDMENT

Hon. Commissioner of Patents Washington, DC 20231

Sir:

Prior to examination, kindly amend the claims as follows.

## **IN THE CLAIMS**

Please cancel all of original claims 1-20 and enter the following new claims 21 to 69:

- 21. A method of treating B cell lymphoma in a human subject comprising administering a chimeric anti-CD20 antibody having a variable light chain comprising the amino acid sequence encoded by the nucleic acid sequence in SEQ ID NO:6 and a variable heavy chain encoded by the nucleic acid sequence in SEQ ID NO:9.
- 22. The method of Claim 21 wherein said B cell lymphoma is relapsed B cell lymphoma.
- 23. The method of Claim 21 wherein said chimeric anti-CD20 antibody is administered parenterally.

- 24. The method of Claim 23 wherein parenteral administration is selected from the group consisting of intravenous, intramuscular, rectal, vaginal, subcutaneous and intraperitoneal.
- 25. The method of Claim 23 wherein administration is by intravenous administration.
- 26. The method of Claim 21 wherein said chimeric anti-CD20 antibody is administered in a single dosage.
- 27. The method of Claim 26 wherein said dose ranges from about 0.001 to 30 mg/kg body weight.
- 28. The method of Claim 26 wherein said dosage ranges from about 0.01 to about 25 mg/kg body weight.
- 29. The method of Claim 26 wherein said dosage ranges from about 0.4 to about 20.0 mg/kg body weight.
- 30. A method for treating a peripheral blood B cell disorder comprising a chimeric anti-CD20 antibody having a variable light chain comprising the amino acid sequence encoded by the nucleic acid sequence in SEQ ID NO:6 and a variable heavy chain encoded by the nucleic acid sequence in SEQ ID NO:9.
- 31. The method of Claim 30 wherein said chimeric antibody is administered together with chemotherapy or radiotherapy.
- 32. The method of Claim 30 wherein said chimeric anti-CD20 antibody is administered parenterally.
- 33. The method of Claim 32 wherein parenteral administration is selected from the group consisting of intravenous, intramuscular, rectal, vaginal, subcutaneous and intraperitoneal.
- 34. The method of Claim 32 wherein administration is by intravenous administration.

- 35. The method of Claim 30 wherein said chimeric anti-CD20 antibody is administered in a single dosage.
- 36. The method of Claim 35 wherein said dose ranges from about 0.001 to 30 mg/kg body weight.
- 37. The method of Claim 35 wherein said dosage ranges from about 0.01 to about 25 mg/kg body weight.
- 38. The method of Claim 35 wherein said dosage ranges from about 0.4 to about 20.0 mg/kg body weight.
  - 39. The method of Claim 21 which additionally comprises radiotherapy.
  - 40. The method of Claim 21 which additionally comprises chemotherapy.
  - 41. The method of Claim 30 which additionally includes radiotherapy.
  - 42. The method of Claim 30 which additionally includes chemotherapy.
- 43. The method of Claim 21 wherein said chimeric anti-CD20 antibody is administered in several dosages.
- 44. The method of Claim 43 wherein said doses are administered over a time period of about one to four weeks.
  - 45. The method of Claim 20 wherein the chimeric anti-CD20 antibody is an IgG1.
  - 46. The method of Claim 30 wherein the chimeric anti-CD20 antibody is an IgG1.
  - 47. The method of Claim 21 which comprises the administration of a radiolabel.
- 48. The method of Claim 47 wherein said radiolabel is attached to said chimeric anti-CD20 antibody.
- 49. The method of Claim 47 wherein said radiolabel is attached to a different anti-CD20 antibody.
  - 50. The method of Claim 49 wherein said different anti-CD20 antibody is murine.

¢

- 51. The method of Claim 50 wherein said murine anti-CD20 antibody comprises the same variable region as said chimeric anti-CD20 antibody.
- 52. The method of Claim 47 wherein said radiolabel is selected from the group consisting of yttrium (90), iodine (131) and indium (111).
  - 53. The method of Claim 52 wherein the radiolabel is yttrium (90).
- 54. The method of Claim 41 wherein said radiolabel is selected from the group consisting of yttrium (90), iodine (131) and indium (111).
  - 55. The method of Claim 54 wherein the radiolabel is yttrium (90).
- 56. The method of Claim 55 wherein the different anti-CD20 antibody is a murine anti-CD20 antibody.
  - 57. The method of Claim 56 wherein the radiolabel is yttrium (90).
- 58. The method of Claim 56 wherein the murine anti-CD20 antibody comprises the same variable region as the chimeric anti-CD20 antibody.
  - 59. The method of Claim 57 which further comprises chemotherapy.
- 60. A method of treating B cell lymphoma comprising administering a therapeutically effective amount of an anti-CD20 antibody comprising a variable light chain comprising the amino acid sequence encoded by the nucleic acid sequence in SEQ ID NO:6.
- 61. A method of treating B cell lymphoma comprising administering a therapeutically effective amount of an anti-CD20 antibody comprising a variable heavy chain encoded by the nucleic acid sequence in SEQ ID NO:9.
  - 62. The method of Claim 60 wherein the antibody is radiolabeled.
  - 63. The method of Claim 61 wherein the antibody is radiolabeled.
  - 64. The method of Claim 60 which additionally includes chemotherapy.
  - 65. The method of Claim 61 which additionally includes chemotherapy.

- 66. The method of Claim 64 wherein the chemotherapy is selected from the group consisting of doxorubicin, vincristine, cyclophosphamide and prednisone.
- 67. The method of Claim 65 where the chemotherapy is selected from the group consisting of doxorubicin, vincristine, cyclophosphamide and prednisone.
  - 68. The method of Claim 62 wherein the radiolabel is yttrium (90) or iodine (131).
  - 69. The method of Claim 62 wherein the radiolabel is iodine (131) or yttrium (90).

## **REMARKS**

The newly added claims find support from the as-filed specification as follows:

All of claims find explicit support at pages 11-24 of the specification and the

Sequence Listing submitted with the parent application, now U.S. Patent 5,736,137. The

Examiner is respectfully requested to enter this Sequence Listing in this application.

Respectfully submitted,

PILLSBURY WINTHROP LLP

Robin I Teckin

Registration No. 35,030

1600 Tysons Boulevard McLean, Virginia 22102 (703) 905-2000 (703) 905-2500 Facsimile

Date: July 25, 2001